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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/697,923 | 10/29/2003 | Christoph D. Karp | 131-US | 9644 |

32763 7590 11/22/2004

NANOSTREAM, INC.
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EXAMINER

CYGAN, MICHAEL T

ART UNIT PAPER NUMBER

2855

DATE MAILED: 11/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/697,923

Applicant(s)

KARP ET AL.

Examiner

Michael Cygan

Art Unit

2855

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 6-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 6-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The applied reference U.S. 6,184,859 B2 has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

1. Claims 1, 3, 6-12, 21-23, and 27-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ericson (Anal. Chem. 2000) in view of Koehler (U.S. 6,814,859 B2). Ericson teaches a microfluidic HPLC comprising a microfluid separation column having an optical detection region bounded by a transmissive window; see Figure 2. The separation column is filled with stationary phase material formed as a porous monolith by polymerizing continuous beds within the channels of the microchip; see page 83, right hand column. The microchip is substantially planar and formed from a plurality (two) or substantially planar device layers; see Figure 2. Ericson teaches operation at 22 bar, equaling 320 psi; see Figure 9 caption. Ericson teaches the claimed device except for a porous membrane disposed in an adhesiveless, stencilled polymer substrate downstream of the optical detection region and acting to elevate the backpressure.

Koehler teaches a porous membrane disposed in an adhesiveless, stencilled polymer substrate downstream of the separation column; see abstract; Figure 1C; column 3 lines 18-44; and columns 6-9. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a porous membrane disposed in an adhesiveless, stencilled polymer substrate downstream of the separation column as taught by Koehler in the invention taught by Ericson to form the column boundary, since Koehler teaches that this minimizes wicking and is readily bonded.

2. Claims 13-20, 24-26, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ericson (Anal. Chem. 2000) in view of Koehler (U.S. 6,814,859 B2) as applied to claim 1, further in view of Soga (US 2003/0230524 A1). The claims are considered to be taught except for the layers comprising a fluidic distribution network including a plurality of columns leading to a plurality of detection regions each having light source and detector. Soga teaches a HPLC device having a fluidic distribution network comprising mobile phase supply, separation columns, optical detection regions each having light source and detector; see entire document, especially Figure 1, paragraphs 0007, 0010-0012, 0025, 0031-0035, and 0038-0044. It would have been obvious to use a fluidic distribution network comprising mobile phase supply, separation columns, optical detection regions each having light source and detector as taught by Soga in the invention taught by Ericson to form a sensing array, since Soga teaches the advantages of speed of processing, high reproducibility, low fluid resistance, and high separation performance; see paragraph 0007.
3. Claims 27-30 and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ericson (Anal. Chem. 2000) in view of Shimada (US 4,137,161) and Hu (U.S. 6,623,860 B2). Ericson teaches a microfluidic HPLC comprising a microfluid separation column having an optical detection region

bounded by a transmissive window; see Figure 2. The separation column is filled with stationary phase material formed as a porous monolith by polymerizing continuous beds within the channels of the microchip; see page 83, right hand column. The microchip is substantially planar and formed from a plurality (two) or substantially planar device layers; see Figure 2. Ericson teaches operation at 22 bar, equaling 320 psi; see Figure 9 caption. Ericson teaches the claimed device except for a porous material disposed downstream of the optical detection region and acting to elevate the backpressure, and interpenetrably bound polymer layers holding multiple regions.

Shimada teaches a HPLC device having separation column, optical detection region, and a "flow passage resisting member" which may take the form of a monolithic packed column (a "tube packed with filler") disposed downstream of the optical detection region to elevate the pressure in the detector cell; see Figure 1 and column 2 line 41 through column 3 line 18. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use a second column downstream of the detection region as taught by Shimada in the invention taught by Ericson to form a backpressure column, since Shimada teaches that this allows analysis of solutions which tend to evolve gas; see column 3 lines 13-15.

Hu teaches a separation system having multiple separation channels formed from interpenetrably bound polymer layers; see columns 7-9. It would

have been obvious to one having ordinary skill in the art at the time the invention was made to use multiple separation channels formed from interpenetrably bound polymer layers as taught by Hu in the invention taught by Ericson, to form the structure since Hu teaches that such a structure provides leak proof seals.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1, 3, 6-12, 21-23, and 27-33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 21, 31, and 32 of copending Application No. 10/313,231 in view of claims 1, 4, and 10 of U.S. Patent Number 6,814,859 B2 and in view of Ericson (Anal. Chem. 2000). The '231 application claims the instant invention except for 100 psi operation and use of a polyolefin membrane, and application to HPLC.

Ericson teaches a microfluidic HPLC comprising a microfluid separation column having an optical detection region bounded by a transmissive window; see Figure 2. The separation column is filled with stationary phase material formed as a porous monolith by polymerizing continuous beds within the channels of the microchip; see page 83, right hand column. The microchip is substantially planar and formed from a plurality (two) or substantially planar device layers; see Figure 2. Ericson teaches operation at 22 bar, equaling 320 psi; see Figure 9 caption. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use HPLC modifications as taught by Ericson in the invention claimed by the '231 application, since Ericson teaches HPLC as an advantageous use for a microfluidic system.

The '859 patent claims 100 psi operation and use of a polyolefin membrane in a microfluidic separation device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use 100 psi operation and use of a polyolefin membrane in a microfluidic separation device as claimed by the '859 patent in the invention claimed in the '231 application to form the stationary phase boundary, since such would ensure containment of stationary phase material while allowing fluid flow.

This is a provisional obviousness-type double patenting rejection.

5. Claims 13-20, 24-26, and 34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 21, 31, and 32 of copending Application No. 10/313,231 in view of claims 1, 4, and 10 of U.S. Patent Number 6,814,859 B2 and in view of Ericson (Anal. Chem. 2000), further in view of Soga (US 2003/0230524 A1). The claims are considered to be taught except for the layers comprising a fluidic distribution network including a plurality of columns leading to a plurality of detection regions each having light source and detector. Soga teaches a HPLC device having a fluidic distribution network comprising mobile phase supply, separation columns, optical detection regions each having light source and detector; see entire document, especially Figure 1, paragraphs 0007, 0010-0012, 0025, 0031-0035, and 0038-0044. It would have been obvious to use a fluidic distribution network comprising mobile phase supply, separation columns, optical detection regions each having light source and detector as taught by Soga in the invention taught by Ericson to form a sensing array, since Soga teaches the advantages of speed of processing, high reproducibility, low fluid resistance, and high separation performance; see paragraph 0007.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Cygan whose telephone number is (571) 272-2175. The examiner can normally be reached on 8:30-6 M-Th, alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Edward Lefkowitz can be reached on 571-272-2180. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MICHAEL CYGAN, PH.D.
PRIMARY EXAMINER